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# Congress of the United States

## House of Representatives

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February 26, 2002

The Honorable Tommy G. Thompson  
Secretary, Department of Health and Human Services  
200 Independence Avenue, SW  
Washington, D.C. 20201

The Honorable Mitchell E. Daniels  
Director, Office of Management and Budget  
725 17<sup>th</sup> Street, NW  
Washington, D.C. 20503

Dear Secretary Thompson and Director Daniels:

It has come to our attention that the Office of Management and Budget (OMB) is currently reviewing proposed changes to the medical records confidentiality rule (45 CFR Parts 160 through 164 Final Rule) as part of a Notice of Proposed Rulemaking (NPRM). This provides an opportunity to ensure that patients' sensitive medical information is protected and that life-saving health research will continue to advance unabated.

Last May, we wrote a comprehensive letter to President Bush (attached) detailing our concerns with the final rule, including:

- Patient consent requirements;
- Clear standards for "minimum necessary" use and disclosure of information;
- Requirements for business associates;
- Coverage of oral communications; and
- Advisory opinions for conflicting state standards.

We still believe these issues remain problematic. In fact, after speaking to providers, practitioners and researchers, we are convinced the rule is unworkable and will greatly damage health outcomes with little gained. Since our last letter, we are even more certain this rule will cause great damage to medical research and are recommending additional changes to the regulation.

Below we highlight our specific concerns related to the rule's impact on medical research. Improved biomedical, epidemiological and outcomes research is critical to provide high quality medical care in the Medicare program and for private sector entities. In addition, advances in medical technology provide an opportunity to reduce Medicare

program costs as beneficiaries remain healthy and avoid costly interventions in expensive settings such as hospitals and skilled nursing facilities. The current medical records confidentiality rule runs counter to these shared goals by inhibiting the flow of information necessary to conduct biomedical research. This will unnecessarily harm patient care and increase health costs, including the costs of the Medicare program.

There are four main problems with the current confidentiality rule that we believe may have the potential to significantly harm health research:

- the definition of "de-identified" information;
- the transition rules for existing medical records;
- new requirements for research protocols subject to Institutional Review Board (IRB) review;
- barriers for reporting information to health registries.

It is critical these problems are addressed prior to moving forward with any final rule.

### *Change the requirements related to de-identified data.*

**Recommendation:** Because removing all identifiers makes research virtually impossible, we recommend modifying the definition of de-identified to require direct identifiers such as name and health plan number be removed, but that indirect identifiers critical to advancing patient research remain.

#### **Issue**

The confidentiality rule makes it extremely difficult and potentially much more costly for researchers to perform broad-based studies that involve patient medical records rather than the patient themselves.

The regulation creates two processes for de-identifying medical information. The regulation requires nineteen different fields of information to be stripped from a patient's medical file in order to be considered de-identified. Alternatively, a statistician may use generally accepted statistical methods to certify that information is not identifiable if the risk of re-identification is "very small." Once a patient's medical record has been de-identified, information about the patient can be used freely, without the myriad restrictions imposed by the rule.

The requirement to delete the nineteen fields or that an individual can hypothetically be identified renders the medical records of little value. For example, researchers use zip codes and infant birth dates in epidemiological and clinical research, including biological and infectious disease tracking. Inclusion of birth date, date of admission, date of discharge, date of diagnosis, and/or other dates are necessary for investigators to conduct longitudinal studies that allow researchers to use historical medical data in developing new treatments. For example, patients treated for brain cancer with a combination of

pharmaceutical and radiation therapy ten years ago, may provide new insights for researchers developing new biological products today.

The final rule requires not only the removal of important identifiers, but also requires that the entity not have knowledge that the data could be used alone or in combination with other information to identify an individual. Conceivably, any data set could be used or combined with other data to ultimately identify an individual. And while we would agree that any determined individual, including biomedical researchers, could conceivably link a patient's diagnosis with a zip code, for example, the goal of public policy relating to confidentiality protections should be to *prohibit or punish* inappropriate disclosure, not *potential* misuse. In this regard, the very structure of the rule points to its inherent weakness, and need for fundamental reform.

### ***Grandfather existing medical records for purposes of the consent requirements.***

**Recommendation:** Grandfather the use and disclosure of existing archival information for research purposes.

#### **Issue**

The rule allows covered entities to rely on patient consent acquired prior to the effective date of the regulation for use of archived medical files. The continued legitimacy of the preexisting consent is limited, however, to the purposes specifically spelled out by the consent. The information in these medical records is used to conduct outcomes research for hospitals and clinics, but more often than not for biomedical research used to develop new drugs and biologics. In general, patient consent for research purposes has historically not been obtained, thereby invalidating use of this data under the transition provision. Vast amounts of important data will be lost to the research community as it will be impossible to obtain new consent for each record from each patient who may have moved, died, or will simply refuse to authorize use of his or her information. This data is critical to research of the health break-throughs of tomorrow.

While HHS contends consent for treatment, payment or health care operations obtained prior to the regulation's compliance date would remain valid for future use, according to an analysis by the General Accounting Office, only 45 percent of most patient consent forms specifically deal with health care operations. A majority of records would still be excluded under the transition rule. Existing records should be grandfathered.

### ***Additional Burdens on IRBs are Duplicative and may be Unnecessary***

**Recommendation:** Establish a "regulatory authorization" structure to allow covered entities to use patient information for several defined purposes. Eliminate the requirement for IRBs to evaluate the potential risk of loss of privacy to the individual versus the potential benefit of the research to the individual.

## Issue

Under the final rule, health researchers are required to obtain an individual's authorization or waiver of authorization from an IRB or privacy board — in addition to the informed consent obtained or waived under the Common Rule — to access and use protected health information for human subjects research. As a result, two entirely separate consents and an authorization are now required of each research participant: informed consent to participate in research under the Common Rule, consent from the patient to the provider in order to be treated to generate research data, and “authorization” for certain medical information to be disclosed and used for research under the regulation, unless the IRB waives the authorization requirement. For the IRB to waive the authorization requirement under the rule, the IRB must consider several new criteria in order to protect the individual's privacy.

For example, the rule requires IRBs to evaluate the potential risk of loss of privacy to the individual versus the potential benefit of the research to the individual. This is an impossible task. Consider, for example, if the individual is in a control group receiving a placebo. In this case, there is conceivably *no* benefit of the research to that particular individual. This requirement should be removed. In either case, the requirements of the rule are duplicative of the consent obtained to conduct human subject research and represent a new requirement placed on already overburdened IRBs.

We once again call for a “regulatory authorization” structure to eliminate this problem.

## *Allow unrestricted reporting to health registries*

**Recommendation:** Allow reporting to all public health registries without patient consent.

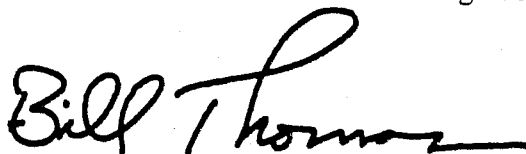
## Issue

The confidentiality rule allows reporting to public health registries established for post-marketing surveillance of Food and Drug Administration (FDA) regulated products. This data is used to ensure patient safety and to improve clinical outcomes. Under the rule, disclosures are permitted only to registries that are required or are under the direction of FDA. FDA, however, claims it does not have the authority to require or direct entities except medical device manufacturers, products approved under certain fast-track procedures, and manufacturers of orphan drug products to establish such registries. Reporting to most registries for public health surveillance would be prohibited by the regulation absent specific patient authorization. The rule should be changed to ensure that all reporting to registries are allowable absent patient consent. To do this an exception should be made to allow reporting of necessary or appropriate information to ensure safe and effective use for a product regulated by the FDA.

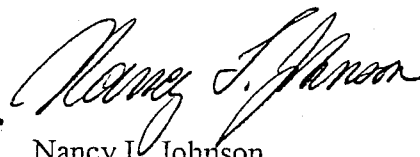
We continue to believe that should it become evident that researchers, providers, health plans and others are unable to comply with any final rule, legislation may be required to restore the balance and trust the regulation seeks to achieve.

We strongly encourage you to adopt the changes outlined above and in the attached letter. Please respond to us within thirty days explaining how the Administration will handle the concerns raised in this letter and the letter we sent you last year.

Best regards,

A handwritten signature in cursive script that reads "Bill Thomas".

Bill Thomas  
Chairman

A handwritten signature in cursive script that reads "Nancy L. Johnson".

Nancy L. Johnson  
Chairman, Health Subcommittee

WMT/jcw  
Attachment